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| 10/593,426 | 06/13/2007 | Fabio Papes | 059994-0155 | 7377 |
| 22428 7590 05/25/2010 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007 | | | EXAMINER ZHENG, LI | |
| | | | ART UNIT 1638 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/593,426

Applicant(s)

PAPES ET AL.

Examiner

LI ZHENG

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 8-17 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 18-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-28 are pending.

Election/Restrictions

2. Applicant's amendment to claims 1-2 in the reply filed on 2/15/2010 is acknowledged.

This application contains claims 8-17 and 28 drawn to an invention nonelected with traverse in Paper filed 4/30/2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-7 and 18-27 are examined on the merits.

3. The objections to the specification and claim 1 are withdrawn due to amendments to the specification and claim 1.
4. The rejections under U.S.C 112, Second Paragraph, are withdrawn due to claim amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

4. Claims 1-7 and 18-27 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A review of the full content of the specification indicates that use of promoters having at least about 65% identity to SEQ ID NO: 2 or being able to hybridizing under stringent condition to SEQ ID NO: 2 is essential for practice the invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." (See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent

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Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

A review of the language of claims indicates that the claims are broadly drawn to a genus of promoter sequences that hybridize under stringent condition to the nucleotide sequence set forth in SEQ ID NO: 2 as well as a genus of promoter sequences that are at least 65% identical to SEQ ID NO: 2.

The specification teaches identification of 12 putative cambium/xylem preferred promoters through bioinformatic analysis of EST clusters (Example 1). The specification further teaches that those 12 promoters were isolated by PCR amplification (paragraphs[0051]-[0052]). The specification further teaches GUS expression assay of those promoters in Arabidopsis plants (Example 4).

However, the specification does not describe the structure of any other species in the claimed genus except for SEQ ID NO:2, itself. Neither the specification nor the prior art teaches the conserved structures that are essential for the promoter activity. The only structures correlated with the promoter activity are the sequence of SEQ ID NO: 2. Not a single specie differing in sequence from SEQ ID NO: 2 and having their promoter activity is described in the specification. Therefore, given the breadth of the claim and the lack of further guidance, a person skilled in the art would conclude that applicants are not in possession of the claimed genera of promoters.

Applicants traverse in the paper filed February 15, 2010. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the specification discloses SEQ ID NO: 2, which is indisputably central and common to the claimed genus. Applicants argue that the specification describes such a genus of polynucleotide in paragraphs [0036] and [0037] and that the specification does indeed correlate structure with function by disclosing "a promoter generally comprises specific signaling sequences called boxes, arranged along the promoter sequence, such that its composition determines the temporal and spatial expression of a gene that is under its regulatory control (response, the paragraph bridging pages 7-8).

The Office contend that SEQ ID NO: 2 is not common to the claimed genus because SEQ ID NO: 2 is not shared by the genus. Further, the specification in paragraphs [0036]-[0037] only describe what are considered as variants of promoter without presenting any species except for SEQ ID NO: 2 itself. Still further the specification does not correlate structure with function. The specification does not describe what are those signaling sequences or boxes in the promoter. Therefore, the Office concludes that Applicants are not in possession of claimed genus.

Applicants further argue that according to the PTO's guidelines for Written Description an Examiner must consider identifying characteristics of an inventive nucleotide. Applicants particularly point to Example 11A of the guideline which provides written description for percent identity claims (response, page 9, 1st paragraph).

The Office contends that the rejection was made according to the guideline. Applicants fail to identify characteristics for claimed promoters. Further, Example

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11A is not applicable to instant rejection because the polynucleotide sequence in Example 11A encodes a polypeptide whereas the instant polynucleotide is a promoter sequence which does not encode any polypeptide.

Scope of enablement

7. Claim 1-7 and 18-27 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 2 and a fragment thereof having cambium/xylem preferred promoter in plant and the plants and bacteria as the transgenic host comprising the promoter, does not reasonably provide enablement for any other variants of SEQ ID NO: 2 having cambium/xylem promoter activity or transgenic host cell other than plants and bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The specification teach identification of 12 putative cambium/xylem preferred promoters through bioinformatic analysis of EST clusters (Example 1). The specification further teach that those 12 promoters were isolated by PCR amplification (paragraphs[0051]-[0052]). The specification further teach GUS expression assay of those promoters in Arabidopsis plants (Example 4).

The claims are broadly drawn to a genus of promoter sequences that hybridize under stringent condition to the nucleotide sequence set forth in SEQ ID NO: 2 as well as a genus of promoter sequences that are at least 65% identical to SEQ ID NO: 2.

Further, without defining hybridization condition, functional equivalent and substantial similarity, the claims reads on any constitutive promoter. The specification clearly does not teach all constitutive promoters. Undue experimentation would be required to determine all the constitutive promoters in all plant.

Furthermore, even the hybridization condition were defined to be a stringent one, it would still not be enabled. The state-of-the-art teaches isolating DNA fragments using stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al. (1999, Plant Molecular Biology 40 :857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65⁰C (page 859, left column, 2nd paragraph). Fourgoux-Nicol et al also teach that the probe and

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isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotides mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2). In the present example, the isolated fragment of Frougoux-Nicol et al exhibits less than 50% sequence identity with the probe to which the fragment hybridized. It is well known in the art that the promoter element essential for its function could be very small (Kim et al. 1994, *Plant Molecular Biology* 24: 105-117, abstract). For example, the DNA that has at least 50% sequence identity to the nucleotide sequence of SEQ ID NO: 2 could have more than 1255 unmatched bases that are scattered along said nucleotide sequence. Since neither the specification nor the prior art teaches all the motifs required for promoter activity, it is not known which bases are indispensable for such promoter activity along the promoter region and which bases are not. Therefore, in the absence of further guidance, undue experimentation would be required by one skilled in the art to make and use the claimed invention with DNA that has at least 50% sequence identity to the nucleotide sequence of SEQ ID NO: 2.

Further, the specification did not indicate that reverse complement DNA strands of SEQ ID No. 2 also have promoter activity, so nucleotide sequences hybridizable to SEQ ID No. 2 are expected to be reverse complement to those sequences and therefore is unlikely to have promoter activity. Undue

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experimentation would be required to use nucleotide sequences hybridizable to SEQ ID No. 2 to produce constitutive expression cassettes.

Further, the claimed expression cassette is for regulating cambium/xylem preferred expression in plants, however, instant claims read on any transgenic host cell. The transgenic non-plant cell such as mammals, nematodes and fungal cells are not enabled since a plant promoter is not expected to function similarly in other host cells including unicellular organisms which do not form tissues.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Applicants traverse in the paper filed February 15, 2010. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that Applicants are not required to provide examples for every embodiment disclosed (response, page 10, 3rd paragraph).

The Office contends that Applicants are not required to provide examples for every embodiment disclosed, however, Applicants fail to provide guidance on how to make those variant having the same promoter activity as that of SEQ ID NO: 2.

Applicants further argue that sequence software programs are available so that a person skilled in the art could be able to identify which nucleotide in SEQ ID NO: 2 could withstand modification and yet still produce a functional promoter (response, page 10, last paragraph).

The Office contends that the software such as Blastn only allow a person skilled in the art to identify homology between two sequences without the ability for identifying which nucleotide in SEQ ID NO: 2 could withstand modification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7 and 18-27 remain rejected under 35 U.S.C. 102(b) as being anticipated by Xue et al (2002, US Patent Number 6,420,629).

Xue et al. disclose that 4CL promoter that is highly specific for xylem expression in tobacco (column 8, lines 62-64). Xue et al. also disclose expression vector using 4CL promoter and transgenic spruce expressing the vector (column 12, lines 33-58). Given that without a defined stringent condition, any sequence can hybridize to another sequence, the claims read on any sequence with plant promoter activity. The reference thus meets all the limitations set forth by instant claims.

Applicants traverse in the paper filed February 15, 2010. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that because Xue et al. do not disclose the nucleotide sequence of SEQ ID NO: 2, the reference could not anticipate the claimed invention (response, page 11, last paragraph).

The Office contends that given that without a defined stringent condition, any sequence can hybridize to another sequence, therefore the claims read on any sequence with plant promoter activity. The reference thus meets all the limitations set forth by instant claims.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David H Kruse/
Primary Examiner, Art Unit 1638